

Lyophilisates having improved reconstitutability

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5 *> This application is a 371 of PCT/EP00/00569, filed 01/26/2000, which claims foreign priority of Germany 19903275.0, filed 01/28/1999.*
The present invention relates to lyophilisates having an improved dissolution rate and reconstitutability, and to a process for their preparation.

10 Lyophilisation, also known as freeze drying, is a long-known and widely used method for the preservation of certain substances under gentle conditions, such as, for example, heat-sensitive foods or especially medicaments. In this method, the substances are dried in the frozen state and can be restored into the original state particularly easily on addition of water or another solvent. In this method, the first
15 step is generally freezing of the starting materials at temperatures down to -70°C . The water is subsequently removed from them by sublimation during the drying process, which is carried out in pressure-tight containers (lyophilisators) under a high vacuum, giving the freeze-dried substance.

20 Lyophilisation is employed in particular for the preservation of sensitive medicaments, since it is very important in the case of medicaments in particular that they do not change during storage, i.e.
25 their structure does not change, rearrange or even decompose, which would mean a considerable impairment with respect to their efficacy.

30 Efforts are always made during freeze drying to incorporate the largest possible amount of active ingredient into the smallest possible volume. This results in concentrations in the vicinity of the saturation concentration of the active ingredient often being employed. This is necessary for the economic efficiency of the processes.

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